

Application No.: 10/657,075

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in this application:

1-40. Cancelled

41 (original). A process for making pharmaceutically acceptable spherical pellets, which comprises:

- (1) combining a solvent, a pharmaceutically active agent and/or its pharmaceutically acceptable salt, and at least one pellet forming carrier to form a wet mixture, wherein the solvent is not combined by spraying;
- (2) stirring, chopping, or both, the wet mixture to form monolithic, spherical wet pellets; and
- (3) drying said wet pellets to form said pharmaceutically acceptable pellets.

42 (original). The process according to claim 41, wherein said solvent is water.

43 (original). The process according to claim 42, wherein said combining step comprises dumping water onto a homogenous dry blend of pharmaceutically active agent and/or its pharmaceutically acceptable salt and at least one pellet forming carrier to form said wet mixture.

44 (original). The process according to claim 43, wherein said dumping of water comprises adding water at a rate within the range of 1 to 1200 seconds per liter.

45 (original). The process according to claim 44, wherein said rate is within the range of 20 to 120 seconds per liter.

46 (original). The process according to claim 43, wherein additional water is dumped onto said wet mixture during said stirring or chopping step (2).

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47 (original). The process according to claim 41, wherein said stirring or chopping step (2) comprises a total of 1 to 60 minutes of stirring, chopping, or combination thereof.

48 (original). The process according to claim 47, wherein said stirring or chopping step (2) comprises a total of 5 to 20 minutes of stirring, chopping, or combination thereof.

49 (original). The process according to claim 41, wherein said drying is carried out by heating, applying microwave or infrared energy, applying vacuum or reduced pressure, passing an inert gas over the wet pellets, or a combination thereof.

50 (original). The process according to claim 49, wherein said drying step comprises heating under reduced pressure while passing nitrogen gas over said wet pellets and applying microwave energy.

51 (original). The process according to claim 41, wherein said pellet forming carrier is microcrystalline cellulose.

52 (original). The process according to claim 51, wherein said pharmaceutically active agent is selected from the group consisting of acarbose, alprostadil, amlodipine, artemotil, atorvastatine, benzodiazepines, citalopram, cladribine, clopidrogel, candesartan, carvedilol, desogestrel, dextrazoxane, diltiazem, dofetilide, donepezil, eprosartan, etanercept, etidronate, exemestane, latanoprost, leflunomide, letrozole, lovastatin, mirtazepine, modafinil, nateglinide, nimesulide, nizatidine, olanzapine, olopatidine, orlistat, oxybutynin, pramipexol, paroxetine, pioglitazone, quetiapine, reboxetine, rimoxypride, repaglinide, risperidone, rizatriptan, ropinirol, rosiglitazone, simvastatin, tamsulosin, telmisartan, tibolone, thalidomide, tolterodine, venlafaxine, zaleplon,

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ziprasidone, zolpidem, zonisamide, zopiclon, and pharmaceutically acceptable salts thereof.

53 (original). The process according to claim 51, wherein said pharmaceutically active agent is a rapidly acting hypnotic.

54 (original). The process according to claim 53, wherein said hypnotic agent is contained in an amount of from 1 to 50 % by weight and together said hypnotic agent and said microcrystalline cellulose account for at least 90 % of said pellets weight.

55 (original). The process according to claim 54, wherein said hypnotic agent is zolpidem free base or zolpidem hydrogentartrate.

56 (original). The pellet made by the process of claim 54.

57 (original). The pellet made by the process of claim 45.

58 (new). The process according to claim 41, which optionally further comprises separating said dried pharmaceutically acceptable pellets and wherein said pharmaceutically acceptable pellets have an average diameter from 0.5 to 2.0 mm.

59 (new). The process according to claim 41, wherein said solvent is combined without the use of a flow restraining device.

60 (new). The pellet made by the process of claim 52, wherein said pharmaceutically active agent is selected from the group consisting of tamsulosin, venlafaxine, zopiclon, and pharmaceutically acceptable salts thereof.